



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61M 1/10, A61N 1/365		A1	(11) International Publication Number: WO 00/69490
			(43) International Publication Date: 23 November 2000 (23.11.00)
(21) International Application Number: PCT/IB00/00658 (22) International Filing Date: 17 May 2000 (17.05.00) (30) Priority Data: 60/134,746 18 May 1999 (18.05.99) US 60/147,703 6 August 1999 (06.08.99) US (71) Applicant (for all designated States except US): SONOMETRICS CORPORATION [CA/CA]; 135-4056 Meadowbrook Drive, London, Ontario N6L 1E4 (CA). (72) Inventor; and (75) Inventor/Applicant (for US only): SMITH, Wayne, L. [CA/CA]; 60 North Center Road, London, Ontario N5X 3W0 (CA). (74) Common Representative: SONOMETRICS CORPORATION; Attn: Jay Ryan, c/o Arter & Hadden LLP, 1100 Huntington Building, 925 Euclid Avenue, Cleveland, OH 44115 (CA).		(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published With international search report.	
(54) Title: SYSTEM FOR INCORPORATING SONOMICROMETER FUNCTIONS INTO MEDICAL INSTRUMENTS AND IMPLANTABLE BIOMEDICAL DEVICES			
(57) Abstract A biomedical apparatus is disclosed including an implantable biomedical device for providing biomedical assistance to the body structure and a device controller (54) for regulating the operation of the biomedical device. A sonomicrometer arrangement (50) is provided, in contact with the body structure and in communication with the device controller (54). The sonomicrometer arrangement (50) ultrasonically measures at least one physical parameter of the body structure and provides feedback information to the device controller (54). The device controller (54) then regulates the operation of the biomedical device in response to the feedback information.			
<p>The diagram illustrates a biomedical apparatus. It features a heart (10) with a sonomicrometer arrangement (50) implanted on its surface. The sonomicrometer arrangement (50) is connected to a device controller (54) via a cable. The device controller (54) is further connected to a power source (56) and a ventricular assist device controller and CPU (58). The ventricular assist device controller and CPU (58) is also connected to the power source (56). The sonomicrometer arrangement (50) is shown with multiple transducers (60) in contact with the heart surface.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

5 **SYSTEM FOR INCORPORATING SONOMICROMETER FUNCTIONS INTO
MEDICAL INSTRUMENTS AND IMPLANTABLE BIOMEDICAL DEVICES**

Cross References to Related U. S. Applications

 This application claims the benefit of U. S. Provisional Application No. 60/134,746, filed
May 18, 1999, and U. S. Provisional Application No. 60/147,703, filed August 6, 1999.

10 **Field of Invention**

 The present invention generally relates to enhanced implantable biomedical
devices and instruments, and more particularly to implantable biomedical devices and
instruments having sonomicrometer functions incorporated therein.

15 **Background of the Invention**

 Using the time-of-flight principle of high frequency sound waves, it is possible to
accurately measure distances within an aqueous medium, such as inside the body of a living
being. High frequency sound, or ultrasound, is defined as vibrational energy that ranges in
20 frequency from 100 KHz to 10 MHz. The device used to obtain dimensional measurements using
sound waves is known as a "sonomicrometer". A typical sonomicrometer uses two or more
piezoelectric transducers that act as transmitters and receivers of ultrasound energy when situated
in a sound-conducting medium and connected to electronic circuitry. The distance between
transducers is measured by first electrically energizing the transmitting transducer, causing it to
25 produce ultrasound energy. The resulting sound wave then propagates through the medium until
it is detected by the receiving transducer. The propagation time of the ultrasound signal, when
multiplied by the velocity of sound in the medium, yields the distance between transducers.

The transducers typically take the form of a piezoelectric ceramic (e.g., PZT or PVDF material) that are energized by a voltage spike, or impulse function of a designated duration. This causes the transducer to oscillate at a characteristic resonant frequency that results in a transmitted signal which propagates away from the transmitter through the medium.

5 The receiver detects the sound energy produced by the transmitter and begins to vibrate in response thereto. This vibration produces an electronic signal on the order of millivolts that can be amplified by appropriate receiver circuitry.

 The propagation velocity of ultrasound in many materials is well documented. The distance traveled by a pulse of ultrasound can therefore be measured simply by recording the
10 time delay between the instant the sound is transmitted and when it is received. This process of transmission and reception can be repeated many times per second. Depending on the embodiment, a large matrix of distances between many transducers can be obtained. In U.S. Patent Nos. 5,515,853; 5,795,298; and 5,797,849 (fully incorporated herein by reference), a procedure is explained for determining the spatial {x,y,z} coordinates for each transducer from
15 the distance matrix.

 Presently, there are several classes of biomedical devices that perform electrical or mechanical activity within the body that do not incorporate dimension-measurement technology as part of their operation. It is believed that the absence of this technology is due to the lack of awareness of sonomicrometry by biomedical engineers, leading to a low appreciation of the
20 utility and benefits of sonomicrometry.

 The present invention addresses the foregoing problem, as well as others, to provide implantable biomedical devices which collect dimension-measurement data using sonomicrometer technology.

25

Summary of the Invention

According to the present invention there is provided an implantable biomedical device which uses sonomicrometry to provide dimension-measurement data that enhances the functionality of the biomedical device.

An advantage of the present invention is the provision of a cardiac pacemaker
5 which is capable of acquiring cardiac dimensional data and calculating from that data parameters such as heart rate, contractile amplitude, contractility, cardiac size, stroke volume and ventricular ejection fraction.

Another advantage of the present invention is the provision of a cardiac defibrillator which is capable of acquiring cardiac dimensional data and calculating from that
10 data parameters such as heart rate, contractile amplitude, contractility, cardiac size, stroke volume and ejection fraction, wherein the cardiac dimensional data and/or computed parameters may be used to determine the need to apply a defibrillation shock, and/or optionally to evaluate post-shock cardiac contractility.

Still another advantage of the present invention is the provision of a ventricular
15 assist device which is capable of acquiring cardiac dimensional data and computed parameters that provide feedback and control information, wherein the information is suitable for determining the appropriate or optimal interaction between the heart and assist device. The nature of this interaction could, for example, pertain to ventricular size, filling or ejection rate, or cardiac output.

Yet another advantage of the present invention is the provision of a post-operative
20 cardiac monitoring device which is capable of acquiring cardiac dimensional data, wall thickness data, and computed parameters such as heart rate, contractile amplitude, contractility, cardiac size, stroke volume and ejection fraction, wherein the cardiac dimensional data and computed parameters can be used to adjust drug doses and treatment protocols during recovery, and to
25 evaluate cardiac function.

These advantages and others are provided by the biomedical apparatus of the present invention in which an implantable biomedical device is provided for providing biomedical assistance to a body structure, and including a device controller for regulating the operating of the biomedical device.

5 A sonomicrometer arrangement is provided, in contact with the body structure and in communication with the device controller. This sonomicrometer arrangement ultrasonically measures at least one physical parameter of the body structure and provides feedback information to the device controller. The device controller regulates the operation of the biomedical device in response to the feedback information.

10 Still other advantages of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description, accompanying drawings and appended claims.

Brief Description of The Drawings

15 Figs. 1A, 1B, 1C and 1D depict typical ventricular assist devices (VADS).

Fig. 2 shows the typical connections made to the heart in a VAD to provide bi-ventricular support.

20 Fig. 3 is a diagram of a VAD incorporating the sonomicrometer arrangement of the present invention.

Fig. 4 is a detailed view showing a transducer of the sonomicrometer arrangement according to an exemplary embodiment of the invention.

25

Detailed Description of the Preferred Embodiment

In accordance with the present invention, sonomicrometer technology (e.g., dimension-measurement transducers and circuitry) is incorporated into implantable biomedical devices. By using dimension-measurement data (e.g., cardiac dimensions, rate of contraction, etc.), the operations of the device are improved (e.g., device control). For instance, defibrillation, rather than pacing, may be implemented based on the presence or absence of contraction in a cardiac muscle. Currently, these conditions are detected electrically, but a mechanical input provides additional information that would be incorporated into a decision tree for the implanted device.

It should be appreciated that while the present invention will be described with particular reference to pacemakers, implantable defibrillators, ventricular assist devices, and post-operative cardiac monitoring methods, the present invention is also applicable to other implantable biomedical devices to provide a sonomicrometer-based dimension-measurement data collection and evaluation system.

A. Inclusion of Dimension Measurement Capability in Ventricular Assist Devices:

Ventricular Assist Devices or VADs (most commonly Left Ventricular Assist Devices or LVADs) perform auxiliary pumping support for the heart by filling the ventricles more completely prior to ventricular systole or by replacing partially or completely the pumping effort of the ventricles. The cardiac dimensional data and computed parameters noted above may be used to provide feedback and control information. This information is suitable for determining, among other items, the appropriate time to stop pumping blood into the ventricles because they have reached a predetermined size. As shown in Figs. 1A-1D, ventricular assist pumps are typically impellers (Figs. 1A and 1B) or diaphragms (Figs. 1C and 1D). They can also be in the form of bladders or bands that inflate under pressure and squeeze the blood chamber that they surround (not shown). In any case, a typical VAD includes a blood pump

that includes an inflow 12 that draws blood from the left ventricle 14 of the heart, and pumps the blood through an outflow 16 into the aorta 18, and out into the body.

Previous-type VADs produce problems known in the literature as pump-induced “ventricular collapse” and also “hyperdilation.” The VAD must withdraw blood from one vessel
5 or chamber in or near the heart and eject this blood into a different chamber or vessel in or near the heart, thereby completing the circulation of blood by bypassing a diseased or non-functional portion of the natural heart. The flow of blood through the body and its return to the inflow region of the VAD is variable and during periods of insufficient return the VAD’s pumping action can collapse the chamber or even the vessel of the inflow region. Another aspect of
10 operation of the VAD is that again due to changes in the blood flow in the body the vessel or chamber that is receiving blood from the outflow of the VAD may expand beyond desired limits, resulting in hyperdilation of the heart chamber or vasculature.

The problem of vascular or chamber collapse or hyperdilation is the result of the VAD being instructed to pump more blood than the current conditions of the vasculature can
15 support or tolerate. When this occurs the controlling mechanism of the VAD must reduce the pumping activity of the VAD. The variability of the patient’s vasculature or the patient’s activity level is the root cause of the need to vary the pumping function of the VAD so as not to cause a condition of collapse or hyperdilation.

Some previous-type devices use ultrasonic or electro-magnetic flow sensors that
20 provide some VAD’s with the feed-back necessary to maintain the desired blood flow to support life and even ambulatory activity, but these sensors do not measure the extent of vascular collapse or hyperdilation. The use of pressure transducers to measure the pressure in the inflow and outflow region of the VAD are extrapolated to give indications of collapse or hyperdilation because it is intuitive that a high pressure will lead to expansion or dilation. However, in reality

the muscle walls of the ventricles and vasculature do not have constant material properties so a direct pressure-volume relationship can not be assumed.

Pressure transducers have commonly been used to solve this problem because of their ubiquitous nature in the biomedical engineering field. However, pressure transducers have a history of drift and attenuated readings when exposed to the natural fibrotic processes of the body over time. The method of direct measurement using sonomicrometers would be preferred since their sensitivity and accuracy does not diminish over time.

An extremely precise measure of the inflow and outflow quantities can theoretically lead to the determination that a flow imbalance is occurring or is about to occur, but even the smallest error in such flow measurements are integrated over time resulting in a feedback mechanism governed by faulty information. Pressure transducers are vulnerable to fibrotic processes that reduce their ability to directly sense the chamber or vascular pressure in question, and their use necessitates that they be placed in the blood stream, which is a surgical complication as well as a thrombolytic risk to the patient. Strain gauges are an alternative way to measure the degree of stretch of a vascular or ventricular structure, but they have a limited range of function and only give measures of relative changes in size. They can also suffer from long-term drift.

Also, the sensation of pressure in the inflow and outflow vessel or ventricle does not give an accurate indication of the degree of collapse or dilation of the vessel or ventricle. Because of this, optimal matching of the inflow and outflow conditions can not be obtained over the wide range of pumping functions required, for example, during outpatient ambulatory activity. The conditions of collapse and hyperdilation can stress or damage the heart muscle, creating a situation that is counter-productive to the overall goal of VAD therapy, which in some cases is to allow a failing heart to regenerate.

The VAD also has inflow and outflow orifices or ports 20, 22, 24, 26 which are directly sewn into specific sites on the heart or the great vessels which come directly off the heart as shown in Fig. 2 for bi-ventricular support. These sites are typically the right atrium 22, the left ventricle 24 (usually the apex), the proximal aorta 24 (usually not above the ascending arch), and the proximal pulmonary artery 26. Fig. 2 shows these sites and the conduits which lead from them to the pumping device. All of these sites and vascular structures are compliant and are also susceptible to damage should they be distended or dilated due to over-filling by the artificial pump. Also, they are as susceptible to collapse leading to the cessation of blood flow if blood is withdrawn from them too quickly. Thus, increased VAD operation can also damage these components.

As is accomplished by the present invention, the addition of sonomicrometer technology allows for the direct measurement of the size of the inflow and outflow regions (be they vessels or chambers) and this information would be used as part of a feedback or control process to regulate the pumping action of the VAD. The present invention is applicable to all types of such devices by providing size, shape, area or volume information on the chamber or vessel they are withdrawing blood from or ejecting blood into. Specifically as used with a bladder type VAD, an important aspect of its operation is that it squeezes it's respective blood chamber when that chamber is sufficiently filled with blood, rather than simply relying on a sensation of pressure within the chamber, which is not a reliable guarantee of sufficient filling. The present invention can monitor the size of the chamber with the appropriate algebraic combination of sonomicrometer length measurements resulting in an aggregate signal indicative of chamber volume. This signal would then be monitored by the VAD controller which would make a decision to activate the bladder when the volume has reached a pre-determined value.

In an exemplary embodiment of the invention, sonomicrometer functions are incorporated into a VAD. The sonomicrometer arrangement measures the distance between

piezoelectric transducers by causing the transducers to send and receive pulses of ultrasound energy between each other. By measuring the transit-time of these pulses through an interposing sound conducting material the distance between these transducers is determined. These transducers would be applied to the vascular or ventricular structures that comprise the inflow and outflow regions connected to the VAD. This enables the continuous determination of size, area, and volume of these structures. These measurements are then incorporated into the control process of the VAD as it operates so as to prevent the occurrence of collapse or hyperdilation of the vascular or ventricular structure in question.

The exemplary embodiment of the present invention is depicted in Fig. 3, in which three separate functional modules are shown which may remain physically separate or be combined as desired to meet ergonomic or reliability or manufacturing criteria. The sonomicrometer 50 includes an associated sonomicrometer control and data processor 52 that performs dimensional measurements of the heart via ultrasonic transducers 54 which have been attached to relevant sites. (For clarity, the inflow and outflow conduits leading to the VAD pumps are not shown, but it should be appreciated that these conduits can be connected in any manner known to those skilled in the art.) Fig. 3 shows an approximate configuration for monitoring four inflow and outflow sites which are typical of bi-ventricular support. The number of ultrasound transducers can optionally be reduced if data from some sites is not required. Also, more than two transducers 60 can optionally be added to a given site in order to provide a more precise measure of area or volume of the relevant structure.

As also shown in Fig. 3, the sonomicrometer control 52 provides a control signal to a VAD controller 54 based on the sonomicrometer data. The VAD controller 54 regulates the operation of the pumping device 10 in such a way as to prevent relevant structures of the heart to not exceed pre-set (or adaptable) size or volume thresholds as reported by the sonomicrometer module, and in a likewise manner to prevent relevant structures to be reduced in size or volume

to the point indicative of collapse. The VAD controller can be adapted to also take in data from other sensor types (not shown) such as pressure transducers or flow sensors, and the VAD controller can then be adapted to combine data from all sources to arrive at an integrated decision making process to control the pumping device.

5 The sonomicrometer control and data processor 52, along with VAD controller 54 and a power supply 56 (preferably a battery) are housed in an electronic module 58 suitable for implantation in the body or outside the body, as determined by necessity, ergonomics or practicality considerations. This housing can be made from metal alloys or plastic polymers. Electrical connections to the housing are to be durable and fully sealed against the intrusion of
10 body fluids and other contaminants. Provisions can be made for auxiliary data connections to allow changes to be made to the programming or functioning of this module by an external computer.

 The electronics module 58 is provided for the sequential transmission and reception of ultrasound signals between the attached piezoelectric transducers 60. In the
15 preferred embodiment, the micro-processor 52 runs an embedded program that controls the operation of the transducers 60. Additionally, in a preferred embodiment, this module is housed within the same enclosure as the VAD controller 60. The piezoelectric transducers 60 are connected via wires to the electronics module 58. The module 58 generates distance data in the form of digital or analog signals by causing the transducers to emit pulses of ultrasound while
20 processing the received signals from non-transmitting transducers. Ultrasound signals in a range of between approximately 1-10 MHz with an amplitude in a range of between approximately 1-50 mV are communicated by receiving transducers to the module. Step-impulse signals on the order of several volts are sent to the transmitting transducers from the module.

 During operation, the electronics module 58 causes the transducers 60 to
25 sequentially emit pulses of ultrasound at a repetition rate from approximately 50 Hz to 500 Hz.

Transducers 60 that are not emitting are instead receiving these acoustic pulses and the received signals are processed and converted to distance signals that are proportional to the distance between the given receiving transducer and the transmitting transducer.

The ultrasonic transducers 60 are configured to measure the physical dimensions
5 of the heart or other body structure during operation of the device. In some of the contemplated embodiments of this invention, several such measurements are combined algebraically to derive a 2-dimensional area or 3-dimensional volume of the body structure. Any of these measurements, or their derivatives, can be further processed to yield the variation (maxima and minima) and rate of change of the heart or other body structure. For example, in one specific
10 arrangement, three transducers 60 can be placed on the body structure to form a triangle, to measure the area enclosed by this triangle. In another specific arrangement, four transducers 60 can be used to model a cylindrical volume corresponding to the heart or other body structure, where the cylindrical volume has a cylindrical cross-section and a length. One pair of transducers 60 is taken to measure the circular cross-sectional diameter and the other pair is taken
15 to measure the length of the cylinder. Of course, it will be appreciated that the transducers 60 can be varied in placement and in number to model any other desired geometrical shapes, such as would occur to those skilled in the art, without departing from the invention.

The distance signal derived from the transducers 60 may be conveyed as a digital unsigned quantity ranging from 8 to 16 bits wide, or it may be conveyed as a uni-polar analog
20 voltage ranging from 0 (zero) to several volts in amplitude. The information provided above is used to determine if the size of measured structures are outside the desired range and, if so, to modify the pump action of the VAD so as to bring the size of these structures back to within the desired range.

The piezoelectric ultrasound transducers 60 can be constructed in a variety of
25 ways, of cylindrical shape in the preferred embodiment. Fig. 4 shows the preferred embodiment

of such a transducer 60. Signal wires 62 are bonded to the inner and outer surface of the transducer 60. For durability purposes, these would be teflon-insulated multi-stranded stainless steel wires arranged as a twisted pair and covered in a silicone jacket. Also shown is a pair of attachment rings 64 for affixing to the surface of the heart, which would also be incorporated into
5 an encapsulation material 66 surrounding the transducer. Other arrangements of attachment mechanisms are possible. The encapsulation material 66 is biocompatible and may consist of injection-formed plastic or epoxy.

The piezoelectric transducers 60 can alternatively be flat or disk-shaped, fabricated from planar stock material, and can be approximately 1 to 2 mm, encapsulated in a
10 material with long-term durability and biocompatibility, such as Teflon™. Two signal wires and possibly a third shield wire will extend from these transducers in a flexible, durable, biocompatible cable and connect to an electronic sonomicrometer module. In this alternative embodiment, the two signal wires are made from 32 gauge stainless steel with a Teflon™ insulation arranged as a twisted pair. This pair is coated with a layer of silastic (silicone) with an
15 over-all diameter of approximately 2 mm. A third wire (un-shielded) coil-wraps the twisted pair along its entire length within the silastic coating. This cable terminates within an electronics control module. This module may be implanted inside the body, or alternatively may be positioned outside the body, in which case these cables will pass through a skin incision or through a connector device affixed to the skin surface.

20 The distance signals generated by the electronics module 58 are conveyed to the VAD controller 54. This conveyance can preferably be in the form of digital data transference on the data bus of the existing control assembly or in the form of an analog voltage signal that is sampled periodically by an Analog-to-Digital converter which is part of the control assembly or control computer.

The microprocessor operation code of the present invention is indicated as follows:

Code inputs (sonomicrometer control module):

- 5 Number of crystals attached to the module;
- Desired data sampling frequency;
- List of dimensions to be output from the module;
- Miscellaneous parameters related to sonomicrometer function;
- Signals to reset the module or suspend it's operation.

10

Code outputs (sonomicrometer module):

- distance data (in analog signal form via DAC or as numeric data);
- computed data (such as algebraic combinations of the distance data).

15 Sonomicrometer module microprocessor code:

 This code takes input parameters and generates distance data or computed data by controlling the sequence of operation of ultrasonic transmission and reception hardware.

20 Code inputs (VAD controller):

- dimension or computed data from sonomicrometer module;
- physiological operating range of structures being measured.

Code outputs (VAD controller):

- 25 A control signal (on/off, true/false, or variable control signal) used as a signal to regulate the pump operation of the VAD. If there are existing regulation signals then this control signal would be added in an appropriately weighed manner to these existing signals.

VAD controller code:

The VAD controller 54 is an existing computational or control module designed specifically for its intended type of VAD pump. Presumably it will always have a feedback
5 process for the regulation of the pumping activity of the VAD, but it is beyond this invention to know how these feedback processes have been implemented.

Other benefits of this invention include the ability to monitor / measure the pumping activity of the natural heart if the VAD fails or if the VAD is turned off to test the capability or degree of recovery of the natural heart. It should be understood and appreciated that
10 the elements and structure of the present sonomicrometric apparatus can be adapted and applied to other implantable biomedical devices to provide a sonomicrometer-based dimension-measurement data collection and evaluation system, as indicated in the following exemplary embodiments, as given below.

15 B. Inclusion of Dimension Measurement Capability in Pacemakers:

Piezoelectric crystals (e.g., PZT or PVDF) are attached to pre-existing pacemaker pacing leads (so that the complexity of the implantation procedure is not increased), or the crystals are attached to separate leads so that they can be more appropriately positioned to
20 measure specific cardiac dimension(s).

Previous patents issued to the assignee of the present application, Sonometrics Corporation, include the ability to sense bio-potentials through the existing metal plating on the crystal, so that the same wires can be used for ECG sensing and sonomicrometer operation with the appropriate multiplexing circuits. These patents include U.S. Patent No. 5,795,298, issued
25 August 18, 1998, which is fully incorporated herein by reference.

A modification of the sonomicrometer measurement is the echo-reflection or single-element range-finder, where dimensions are measured from a single transducer to a selected reflection boundary. For example, this may result in the measurement of cardiac wall thickness at the site of transducer contact.

- 5 Pre-existing microcomputers inside the pacemaker may activate sonomicrometer (or range-finder) circuits continuously, or only during diagnostically relevant times to conserve battery power.

Multiple cardiac dimensions may be measured by increasing the number of transducers providing position data. During operation, the pacemaker may acquire cardiac
10 dimensional data and compute items such as, but not limited to, actual heart beat rate, contractile amplitude, contractility, cardiac size, stroke volume and ejection fraction. This computed data is referred to as "computed parameters." The pacemaker uses the computed parameters to alter its functionality by, for example, deciding when pacing is, or is not, appropriate or indicated. Depending on the capabilities of the pacemaker and the clinical relevancy of the computed
15 parameters, the computed parameters may be stored internally by the pacemaker so that a history or trend of these computed parameters can be clinically assessed. Computed parameters identifying a trend can again be used by the pacemaker to make decisions on when pacing is or is not, appropriate or indicated.

In cases where the ECG signal becomes compromised, the pacemaker may be
20 switched into a mode where its' functionality is determined by the characteristics of the cardiac dimension signal(s) and/or the computed parameters.

C. Inclusion of Dimension Measurement Capability in Implantable Defibrillators:

25 The comments set forth above in section B also apply to an implantable defibrillator. Moreover, a defibrillator can use the cardiac dimensional data and/or the computed

parameters to determine if there is a genuine need to apply a defibrillation shock. Once the shock is given, the subsequent cardiac dimensional data can provide invaluable information on post-shock cardiac contractility.

5 D. Use of Dimensional Measurements during Post-Operative Cardiac Monitoring:

Two or more sonomicrometer transducers and/or one or more wall thickness transducers can be attached to the myocardium during an invasive heart procedure so that the resulting cardiac dimensional data and/or wall thickness data can be measured and parameters
10 such as, but not limited to, heart rate contractile amplitude, contractility, cardiac size, stroke volume and ejection fraction can be computed. This information, and their trends, is displayed to clinicians during the procedure and also post-operatively by way of a bedside monitoring unit. These transducers are later detached from the myocardium and withdrawn through chest tubes that are normally in place post-operatively.

15 The state of the heart can be assessed by knowing the values of the various computed parameters and their trends. This information can be used to adjust drug doses and treatment protocols during recovery without employing more sophisticated diagnostic instruments such as echo-cardiography or Swan-Ganz catheterization. The continuous measurement of cardiac dimensional data during recovery can be tracked and alarms can be set to
20 indicate poor cardiac function that can be acted upon immediately by medical staff.

E. Inclusion of Dimension Measurement Capability in Prosthetic Devices:

Prosthetic devices that undergo shape changes in response to natural forces within
25 the body are carefully designed to be durable for the life of the device. It is stated here that such devices would benefit from the inclusion of dimension-measurement transducers which would provide information on the degree of motion or flexing the device is experiencing. Such

information can be transmitted to a monitor outside the body during clinical evaluation of the device. Pending failure of the device, or indications that the device is functioning outside its design limits, can be indicated by the data from the dimension measurement transducers, enabling medical personnel to take corrective action on the device. Examples of prosthetic
5 devices that would benefit from the inclusion of dimension-measurement transducers are heart valves, vascular stents, and artificial joints.

10 F. Inclusion of Dimension Measurement Capability in Diagnostic, Therapeutic, and Surgical Instruments:

During certain medical procedures it is necessary to position or guide two or more instruments into a region of the body from different entry points or through different pathways. The addition of dimension measurement transducers to these instruments would provide a simple indication of their separation during insertion, manipulation, and positioning, allowing the
15 clinician to position the devices appropriately.

An example would be the placement of a transjugular intra-hepatic portosystemic shunt. Additionally, a previously implanted dimension measurement transducer can act as a locator reference for diagnostic, therapeutic, or surgical instruments, enabling medical personnel to quickly and directly guide the instrument to the vicinity of the transducer.

20 The present invention has been described with reference to preferred embodiments. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. It is intended that all such modifications and alterations be included insofar as they come within the scope of the appended claims or the equivalents thereof.

What is Claimed:

1. A biomedical apparatus comprising:
an implantable biomedical device for providing biomedical assistance to the body
5 structure;
a device controller for regulating the operation of the biomedical device;
a sonomicrometer arrangement, in contact with the body structure and in
communication with the device controller, for ultrasonically measuring at least one physical
parameter of the body structure and providing feedback information to the device controller,
10 wherein the device controller regulates the operation of the biomedical device in response to the
feedback information.
2. The biomedical apparatus of claim 1 wherein the sonomicrometer arrangement
includes a plurality of ultrasonic transducers for respectively sending and receiving ultrasonic
15 signals.
3. The biomedical apparatus of claim 2 wherein the ultrasonic transducers are
piezoelectric transducers for emitting ultrasound signals in a range between about 1-10 MHz with
an amplitude in a range of between about 1-50 mV.
20
4. The biomedical apparatus of claim 2 wherein the ultrasonic transducers are
configured to measure at least one physical dimension of the body structure during operation of
the biomedical device.
- 25 5. The biomedical apparatus of claim 4 wherein the ultrasonic transducers are
configured to measure a geometrical shape being at least one of 2-dimensional and 3-
dimensional.

6. The biomedical apparatus of claim 2 wherein the ultrasonic transducers are encapsulated in a biocompatible material.

5 7. The biomedical apparatus of claim 2 wherein the ultrasonic transducers include a plurality of attachment rings, for affixing to the surface of the body structure.

8. The biomedical device of claim 1 wherein the implantable biomedical device is a ventricular assist device for providing auxiliary pumping support for a heart.

10 9. The biomedical apparatus of claim 1 wherein the device controller is part of an electronics module including a sonomicrometer control and a power supply.

10. The biomedical apparatus of claim 9 wherein sonomicrometer control includes a
15 microprocessor that runs an embedded program that controls the operation of the sonomicrometer arrangement.

11. The biomedical apparatus of claim 10 wherein the embedded program causes the sonomicrometer arrangement to emit ultrasound pulses at a repetition rate of between about 50
20 Hz and about 500 Hz.

12. A biomedical method comprising:
implanting a biomedical device for providing biomedical assistance to a body structure;
25 ultrasonically measuring at least one physical parameter of the body structure;
generating feedback information corresponding to the ultrasonically measured physical parameter; and

regulating the operation of the biomedical device in response to the feedback information.

13. The biomedical method of claim 12 wherein the step of ultrasonically measuring
5 comprises measuring the time of flight of an ultrasonic signal between a plurality of transducers.

14. The biomedical method of claim 12 wherein the step of ultrasonically measuring
at least one physical parameter comprises measuring at least one physical dimension of the body
structure during operation of the biomedical device.

10

15. The biomedical apparatus of claim 14 wherein the step of ultrasonically
measuring at least one physical dimension comprises measuring a geometrical shape being at
least one of 2-dimensional and 3-dimensional.

15 16. The biomedical method of claim 12 wherein the step of implanting comprises
implanting a ventricular assist device for providing auxiliary pumping support for a heart.

17. The biomedical method of claim 16 wherein the step of ultrasonically measuring
comprises measuring the physical dimensions of at least a part of the heart to monitor
20 occurrences of collapse and hyperdilation.

18. The biomedical method of claim 17 wherein the step of regulating comprises
varying the ventricular assist device to prevent collapse and hyperdilation.

25 19. The biomedical method of claim 12 wherein the step of ultrasonically measuring
comprises emitting ultrasound pulses at a repetition rate of between about 50 Hz and about 500
Hz.

1/4

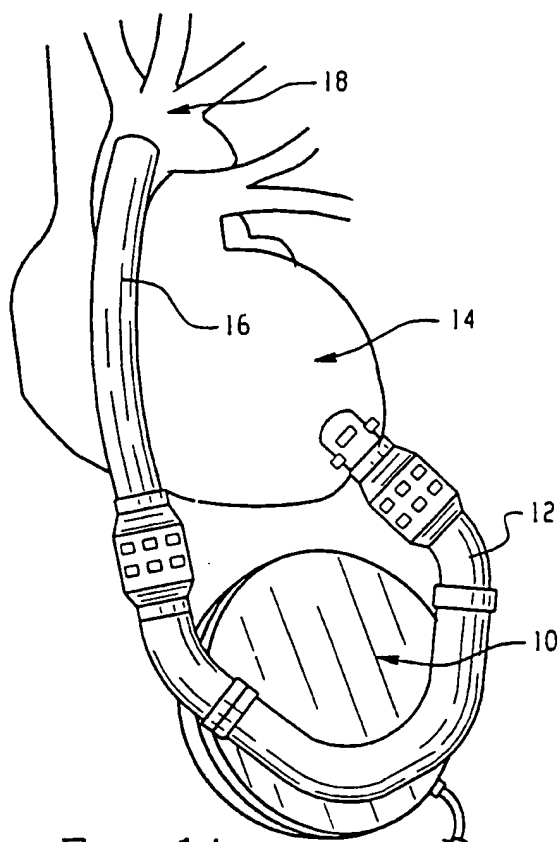


Fig. 1A

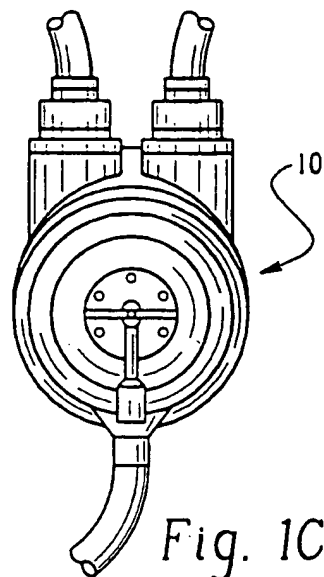


Fig. 1C

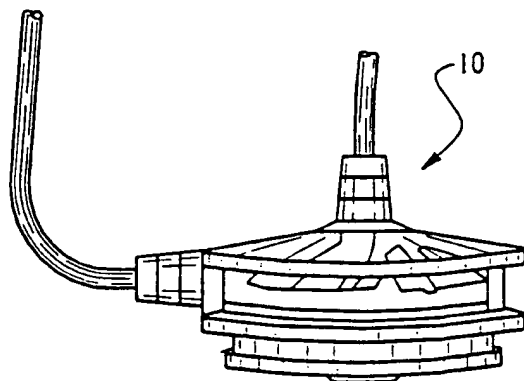


Fig. 1B

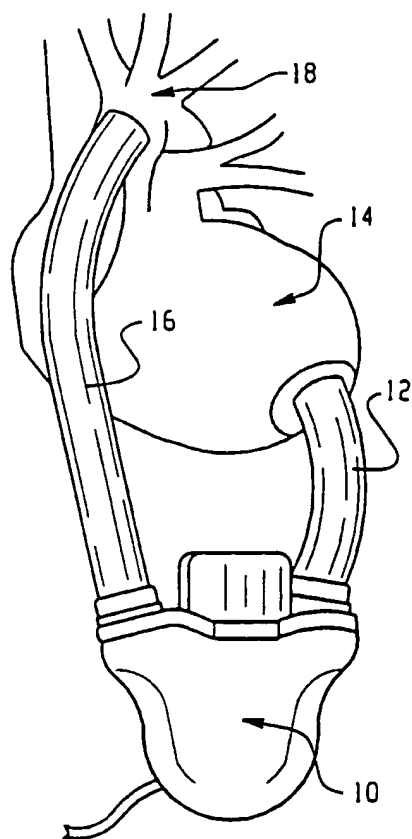


Fig. 1D

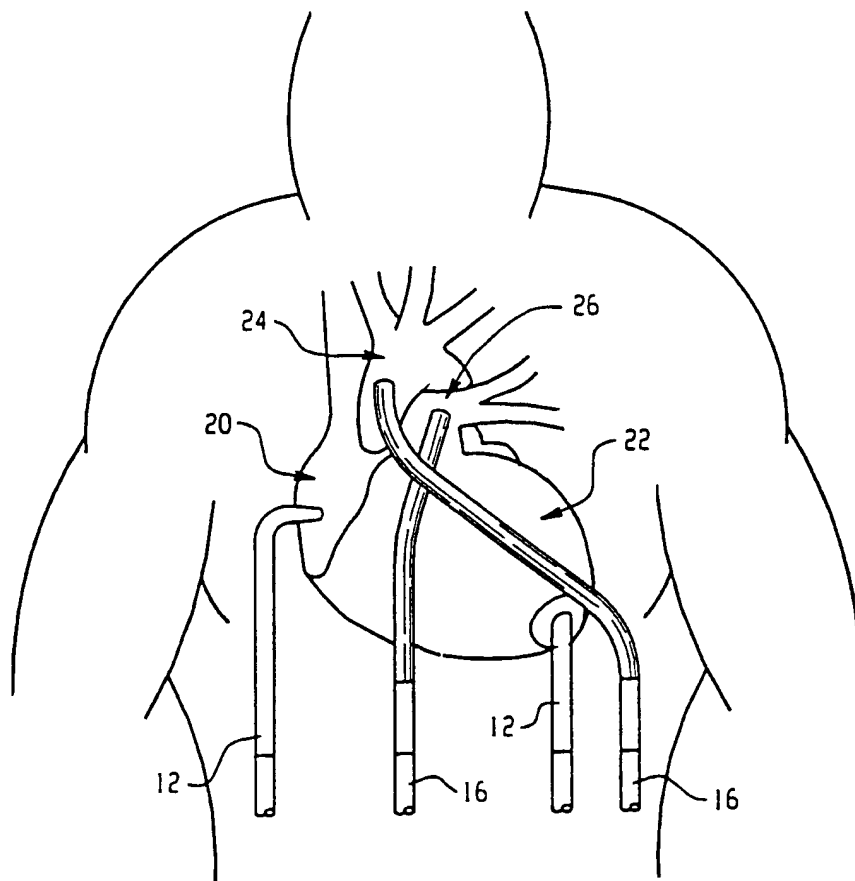


Fig. 2

3/4

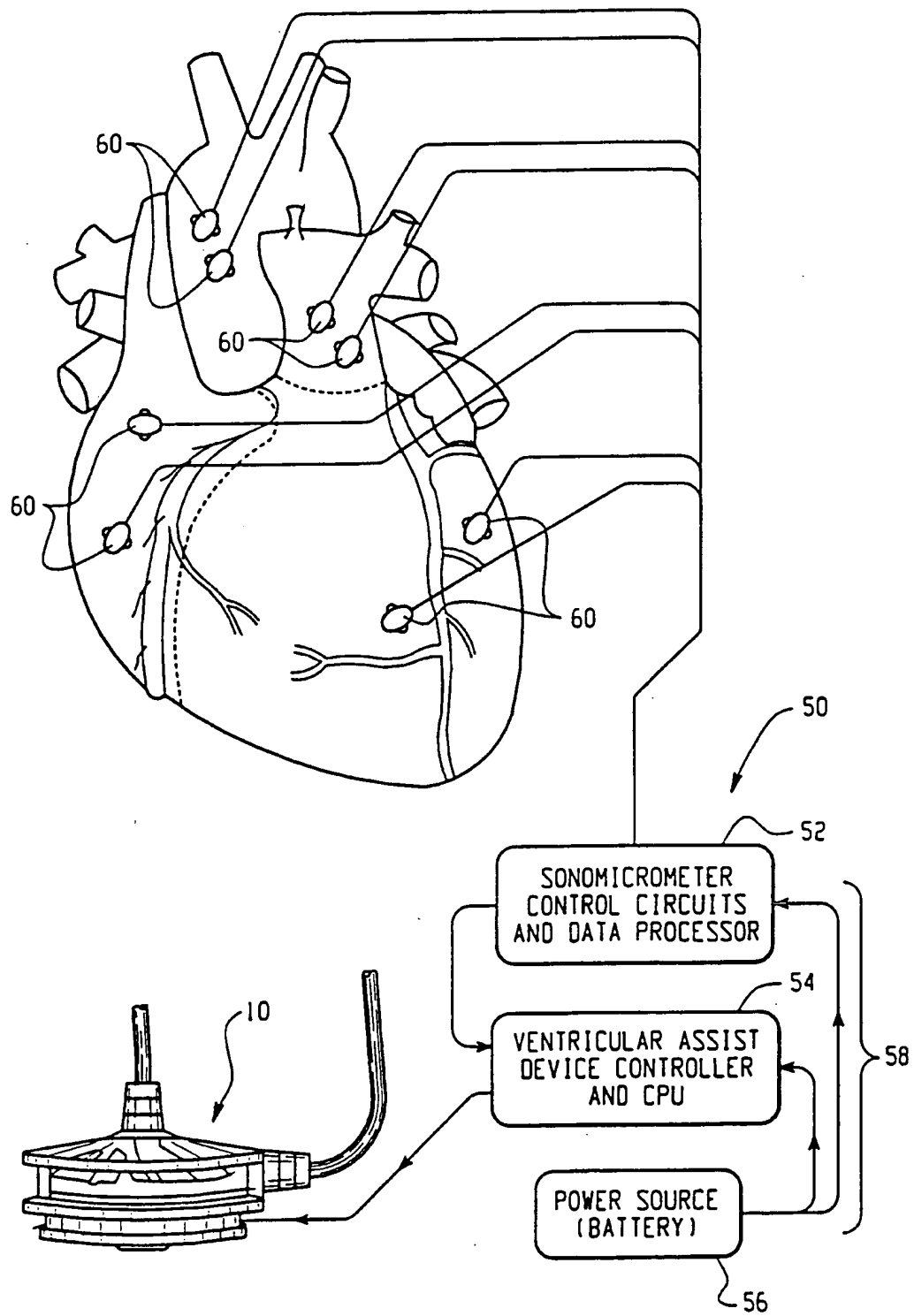


Fig. 3

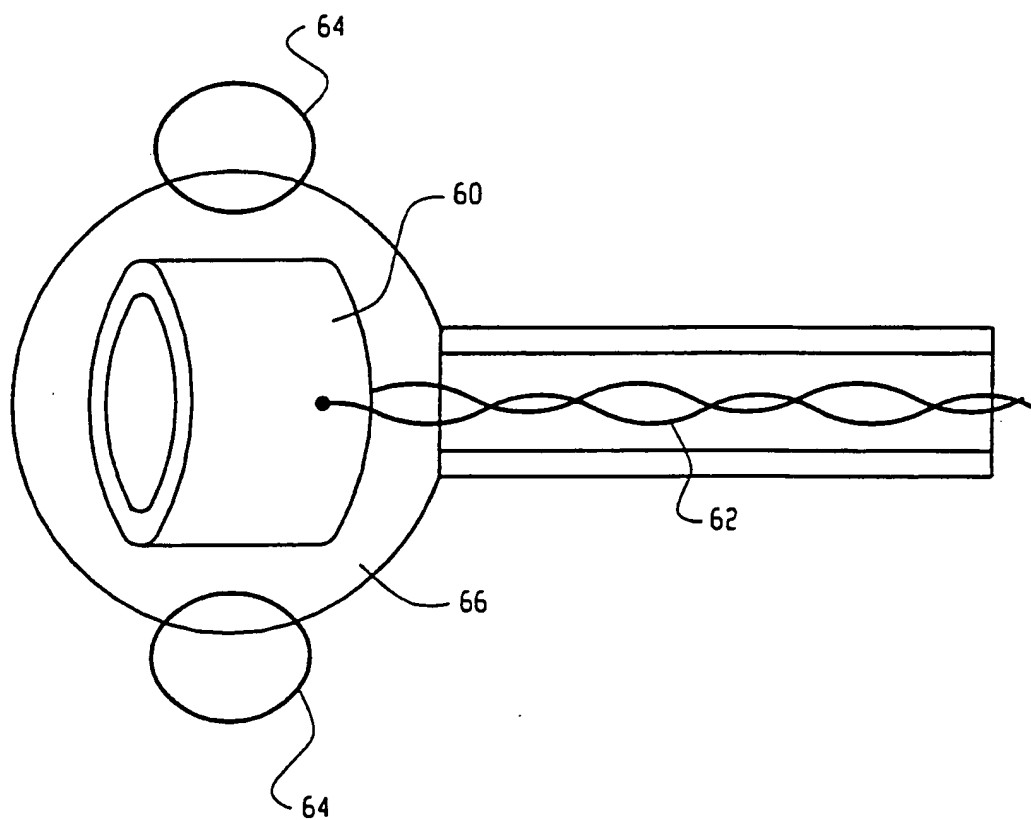


Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/00658

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M1/10 A61N1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61N A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 07285 A (HEMMINGSSON TRYGGVE ;PACESETTER AB (SE)) 18 February 1999 (1999-02-18) page 4, line 14 - line 15 page 9, line 2 -page 11, line 4 figures ---	1-4,8-10
X	US 4 936 304 A (KRESH J YASHA ET AL) 26 June 1990 (1990-06-26) column 1, line 10 - line 15 column 2, line 33 - line 45 ---	1,8
X	EP 0 467 695 A (TELECTRONICS NV) 22 January 1992 (1992-01-22) column 6, line 2 - line 10 column 11, line 24 - line 27 ---	1,8
	-/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

28 August 2000

Date of mailing of the international search report

05/09/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Lakkis, A

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB 00/00658

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 305 745 A (ZACOUTO FRED) 26 April 1994 (1994-04-26) abstract column 9, line 50 - line 57 column 14, line 27 - line 34 ----	1
A	US 4 993 427 A (BARR HOWARD S ET AL) 19 February 1991 (1991-02-19) column 1, line 57 -column 2, line 16 ----	1,7
A	EP 0 536 873 A (TELECTRONICS NV) 14 April 1993 (1993-04-14) column 14, line 34 - line 43 ----	1
A	US 5 156 154 A (VALENTA JR HARRY L ET AL) 20 October 1992 (1992-10-20) ----	
A	US 4 109 644 A (KOJIMA GILBERT K) 29 August 1978 (1978-08-29) ----	
A	US 5 797 849 A (SMITH WAYNE ET AL) 25 August 1998 (1998-08-25) cited in the application ----	
P,X	US 5 928 131 A (PREM EDWARD K) 27 July 1999 (1999-07-27) column 12, line 32 -column 14, line 2 figures 10-12 -----	1,2,4,8, 9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 00/00658

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9907285 A	18-02-1999	EP 0999789 A	17-05-2000
US 4936304 A	26-06-1990	AT 55696 T	15-09-1990
		AU 599341 B	19-07-1990
		AU 6474586 A	24-04-1987
		BR 8606906 A	03-11-1987
		CA 1298878 A	14-04-1992
		DE 3673643 D	27-09-1990
		DK 292787 A	09-06-1987
		EP 0244446 A	11-11-1987
		JP 63502398 T	14-09-1988
		NO 872385 A	05-08-1987
		WO 8701947 A	09-04-1987
EP 0467695 A	22-01-1992	JP 4250169 A	07-09-1992
US 5305745 A	26-04-1994	FR 2632533 A	15-12-1989
		FR 2637807 A	20-04-1990
		AT 103498 T	15-04-1994
		CA 1327838 A	15-03-1994
		DE 68914199 D	05-05-1994
		DE 68914199 T	14-07-1994
		EP 0348271 A	27-12-1989
		JP 2786271 B	13-08-1998
		JP 3055032 A	08-03-1991
US 4993427 A	19-02-1991	NONE	
EP 0536873 A	14-04-1993	US 5215083 A	01-06-1993
		DE 69222253 D	23-10-1997
		DE 69222253 T	05-02-1998
		DE 536873 T	04-11-1993
US 5156154 A	20-10-1992	NONE	
US 4109644 A	29-08-1978	NONE	
US 5797849 A	25-08-1998	US 5515853 A	14-05-1996
		AU 6514298 A	22-09-1998
		WO 9839669 A	11-09-1998
		AU 5140496 A	23-10-1996
		CA 2215508 A	10-10-1996
		WO 9631753 A	10-10-1996
		EP 0879426 A	25-11-1998
		JP 11503629 T	30-03-1999
		US 5830144 A	03-11-1998
		US 5795298 A	18-08-1998
		US 5868673 A	09-02-1999
		US 5817022 A	06-10-1998
		US 5779638 A	14-07-1998
US 5928131 A	27-07-1999	DE 19854724 A	27-05-1999
		FR 2771295 A	28-05-1999
		GB 2335146 A, B	15-09-1999
		GB 2340404 A, B	23-02-2000
		GB 2340405 A, B	23-02-2000
		IT RM980721 A	26-05-1999
		JP 11241695 A	07-09-1999

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 00/00658

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5928131 A		NL 1010651 C NL 1010651 A	06-04-2000 27-05-1999
<hr/>			

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.